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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
07/158,652	02/22/1988	MARC ALIZON	PAST-010-A	3369

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EXAMINER	
FREDMAN, JEFFREY NORMAN	
ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 04/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	07/158,652	ALIZON ET AL.	
	Examiner	Art Unit	
	Jeffrey Fredman	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *March 9, 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *142-151* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *142-150* is/are allowed.

6)☒ Claim(s) *151* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.129(a)

1. Since this application is eligible for the transitional procedure of 37 CFR 1.129(a), and the fee set forth in 37 CFR 1.17(r) has been timely paid, the finality of the previous Office action is hereby withdrawn pursuant to 37 CFR 1.129(a). Applicant's second submission after final filed on March 9, 2006 has been entered.

Status

1. Claims 142-151 are pending.

Claim 151 is rejected.

Claims 142-150 are allowed.

Any rejection which is not reiterated in this action is hereby withdrawn as no longer applicable.

Double Patenting

2. Claim 151 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 6,627,395. Although the conflicting claims are not identical, they are not patentably distinct from each other because:

Claim 1 of U.S. Patent 6,627,395 teaches a method for preparing and detecting HIV-1 RNA from a lysate of an HIV-1 virus, said method comprising:

(a) providing a biological sample that comprises human CD4+ lymphocytes infected with HIV-1 virus;

(b) separating said virus from said human CD4+ lymphocytes;

(c) centrifuging said separated virus to form a fraction comprising concentrated virus;

(d) isolating said fraction comprising concentrated virus;

(e) lysing said virus;

(f) precipitating the RNA of said virus; and

(g) detecting said viral RNA..

This claim represents a species of the current, broader generic claim in which step (a) of claim 1 of U.S. Patent 6,627,395 teaches the step of providing a biological fluid comprisign HIV-1 infected cells, step (b) of claim 1 of U.S. Patent 6,627,395 teaches the step of preparing a cell free supernatant from the biological fluid, step (c)-(d) teach the step of isolating the HIV-1 virions from the cell free supernatant and steps (e) teaches the disruption of the virions to release the HIV-1 RNA. Claims 2-6 of U.S. Patent 6,627,395 demonstrate that multiple isolation methods were contemplated, supporting the broad scope of this double patenting analysis.

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Allowable Subject Matter

2. Claims 142-150 are allowed.

3. The following is a statement of reasons for the indication of allowable subject matter: Claims 142-150 are drawn to specific nucleic acid sequences which comprise a region of the HIV-LTR and additional sequence. The Chang patent, cited as prior art above, does not teach the HIV-LTR sequence with a priority date prior to that of the current application, as Applicant correctly notes. Therefore, the claims are novel and unobvious over the prior art.

Response to Arguments

4. Applicant's arguments filed March 9, 2006 have been fully considered but they are not persuasive.

Applicant argues that a prior art claim to a method of analyzing a "biological sample" would not render prima facie obvious a claim which was drawn to a "biological fluid". First, this argument is not found persuasive because the question is whether an ordinary practitioner would immediately envisage a biological fluid as a biological sample. The premier and first biological sample that would contain lymphocytes is blood. An ordinary practitioner, confronted with a claim in which a biological sample with lymphocytes is required, would interpret this as a blood sample. Second, since, in fact lymphocytes are blood cells themselves, any biological sample containing such cells would necessarily comprise biological fluid since the cells themselves have fluid and are biological in nature. So any sample with lymophocytes would necessarily comprise a "biological fluid". Therefore, the double patenting rejection is maintained.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Fredman whose telephone number is (571)272-0742. The examiner can normally be reached on 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571)272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jeffrey Fredman
Primary Examiner
Art Unit 1637

3/21/06